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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,327	05/25/2000	Neil H. Riordan	RIORD.004A	7262

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/25/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/579,327

Applicant(s)
Riordan et al

Examiner
Mark Navarro

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-66 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Additionally Applicants amendment filed June 24, 2003 (Paper Number 23) has been received and entered. Claims 1-39 have been canceled, and new claims 40-66 have been added. Consequently, claims 40-66 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-21 and 34-39 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of “substantially free of added raffinose and added enzymes.” is withdrawn in view of Applicants amendment.
2. The rejection of claims 1-21 and 34-39 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants amendment.

3. The rejection of claims 1-21 and 34-39 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants amendment.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

4. Claims 55-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly submitted claims recite a final pH of about 1.5 or 2.5. Applicants point to support for the pH limitations on page 11, lines 24-29. It is noted that Applicants recite claims 61-64 on page 6 of the response filed June 24, 2003, however since claims 63-64 do not recite pH limitations this is deemed to be a typographical error and intended to mean claims 54-58. In any

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event page 11 sets forth that the “stomach has a pH of 1.5 to 2.5” and that a “pH of as low as 3 in oral medications are tolerable.” However, reciting what the pH of the stomach is does not provide support for now claiming a final pH of 1.5 or 2.5. Given the logarithmic scale, a pH of 2.0 is ten times stronger than a pH (3.0) of what Applicants have already stated is the low end of orally tolerable medications. Simply put, reciting the pH of the stomach does not correlate with support for claiming an immunogenic composition of the same pH level.

Applicant is required to demonstrate clear support for the pH levels of 1.5 and 2.5, (page and line number) or cancel the newly added material.

5. Claims 40-47 and 49-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing an immunogenic composition from *L. fermentum*, does not reasonably provide enablement for methods of producing an immunogenic composition from any peptidoglycan containing bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the

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invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir. 1999).

First, Applicants sole working examples are directed to immunogenic compositions obtained from *L. fermentum*.

Second, Seager (US Patent Application Publication 2002/0197321) set forth that vaccines incorporate antigens which can be peptides, proteins, or whole or partial fragments or extracts of bacterial cells often attenuated to remove toxic components. A primary problem is ensuring that these antigens or antigenic compounds reach the appropriate site in sufficient quantities to provoke the requisite immune response. (See page 1). Applicants claims are directly analogous to a bacterial extract which must retain antigens or antigenic compounds in sufficient quantities to "stimulate the immune system." As set forth by Seager, this is simply an unpredictable field. Given, that each bacteria has its own unique toxins and antigenic epitopes, extrapolation of a single working example of *L. fermentum* to any peptidoglycan containing bacteria would require excessive experimentation by those of skill in the art to practice the broadly claimed invention.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 40-42, 45-50, 58-61, and 63-65 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Link et al.

The claims are directed to a method for producing an immune stimulating composition comprising treating bacteria containing peptidoglycan with an acid treatment solution; removing insoluble components from the solution resulting from said treating; saving the remaining solution and adjusting to a physiologically acceptable pH; testing said solution for immune-stimulating activity; and obtaining thereby an immune stimulating composition.

Link et al (US Patent Number 5,185,321) disclose of incubating *L. bulgaricus* for 6h at 40°C. The biomass is separated, washed and divided into 2 parts A and B. Part B is suspended in a .01 M acetate buffer at pH 5. The resulting composition is then centrifuged, filtered, and its immunostimulating effect determined in mice. (See claims and columns 3-4).

It is noted that Link et al do not specifically recite “*L. fermentum*.” However, Link et al refer to using the cell wall of lactic acid bacteria, particularly *L. bulgaricus*. The general teaching

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of lactic acid bacteria encompasses *L. fermentum*. It has long been held that a reference must be evaluated in its entirety, not on the basis of its preferred embodiments or working examples. In re Mills, 470 F.2d 649, 651, 176 USPQ 198 (CCPA 1972).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

September 19, 2003